Rejections under 35 U.S.C. § 102 and 103(a) - Krizek et al.

On page 2 of the June 17, 2002 Office Action, the Examiner maintained the rejection of claims 1-2, 6-7, 12, 14-16, 20-21, 26 and 28-31 under 35 U.S.C. 102(b) as being anticipated by Krizek et al.

On page 3, the Examiner maintained the rejection of claims 1-2, 5-7, 9, 12, 14-16, 19-21, 23, 26 and 28-31 under 35 U.S.C. § 103 as allegedly unpatentable over Krizek et al.

The Examiner noted applicants' arguments filed March 26, 2002, that the teaching by Krizek et al. of individual plant transformation with a gene encoding either AP3 or PI, wherein each of these encoded proteins are transcription factors and therefore "regulatory proteins", are prohibited by the claims. However, the Examiner maintained that applicants' claims do not exclude the presence of transcription factors, and that the specification does not define "regulatory protein" to encompass transcription factors. The Examiner noted that the AP3/PI *dimer* is characterized in the instant specification as activating other genes (e.g., page 13 of the specification, lines 10-15), but alleged it is unclear whether each individual protein has that activity. The Examiner also noted that applicants have themselves constructed individual plants transformed with either the entire *AP3* gene or the entire *PI* gene, referring to pages 36-37 of the specification.

In response, applicants point out that at the introduction of the very experiment that the Examiner has cited, Ape3 and Pi are described as being "two proteins ... which are involved in the regulation of floral differentiation", i.e. as each one having a regulatory function. (Emphasis added, p 36, l 4-6).

Moreover, in their specification, applicants clearly state that Ape3 and Pi cannot be used in their invention. Specifically, in the first paragraph on page 4, applicants describe that the "expression of [certain factors R and C1] separately in heterologous plants has some effect on the transcription of endogenous genes"; and the fact that these genes have "some effect in isolation ... may preclude their use for applied purposes." Then, in the very next paragraph on page 4, applicants unambiguously state that the limitations described for factors R and C1 also apply to Ape3 and Pi. Therefore, it is not proper to assert that Ape3 and Pi are included in applicants' pending claims.

Furthermore, the Examiner's assertion that the "specification does not define 'regulatory protein' to encompass transcription factors," is unfounded. Returning to page 36, lines 4-6 of applicants' specification, the acknowledged transcription factors Ape3 and Pi are described as being "two proteins ... which are involved in the regulation of floral differentiation", i.e. as being regulatory proteins (emphasis added).

Finally, the prior art cited, Krizek et al., recognize that transcription factors are regulatory proteins. On page 11, Krizek et al. first describe Ape3 and Pi as belonging to the MADS family of transcription factors, and then outlines their activity to be regulation of organ identity in the whorls of flowers, i.e. to be regulatory proteins.

In view of the foregoing, applicants submit that transcription factors are regulatory proteins, unambiguously, and Ape3 and Pi are excluded from applicants' claimed invention.

Accordingly, the rejection based on Krizek et al. is improper and should be withdrawn.

Rejection under 35 U.S.C. § 103(a) - ALKO/OY ALKO/HIATT et al.

On page 3 of the June 17, 2002 Office Action, the Examiner maintained the rejection of claims 1-2, 5-6, 8-9, 12-16, 19-20, 22-23 and 26-31 under 35 U.S.C. 103(a) as allegedly unpatentable over WO 96/00789 (ALKO GROUP) taken with WO 93/17093 (OY ALKO AB) and Hiatt et al.

The Examiner noted applicants' argument that the cited references fail to teach or suggest individual plants which are transformed with single genes which do not encode active enzymes. However, the Examiner maintained that the references taken together teach that yeast trehalose synthesis enzymes are composed of various subunits, and suggest that individual plants transformed with genes encoding individual subunits of the entire active enzyme may be crossed, in order to produce the entire active enzyme complex in particular tissues or at particular developmental stages, in order to minimize potential toxic effects of prolonged or constitutive trehalose exposure.

In response, applicants traverse this rejection on the basis that none of the references, alone or in combination, teach or suggest every element of applicants' pending claims.

With regard to the continued reliance on WO 96/00789 (ALKO GROUP) as a primary reference, applicants admit to some confusion. WO 96/00789 describes the enzymes trehalose-6-phosphate phosphatase and trehalose-6-phosphate synthase as

subunits of the enzyme trehalose synthase. As explained in applicants' August 23, 2001 Amendment, the trehalose-6-phosphate phosphatase and trehalose-6-phosphate synthase enzymes are themselves active enzymes when expressed separately in a plant. This fact is not contested by the Examiner, as it could not be in view of the explicit teaching, for example, on page 3, lines 31-38, on page 10, lines 17-18, and on page 11, lines 5-7 of WO 96/00789 that each one of these two peptides, separately, is indeed an enzyme. Moreover, WO 93/17093 (OY Alko AB), the second reference relied on by the Examiner, confirms this on page 16, lines 4-6 by specifying that "trehalose-6-phosphate synthase (TPS) and trehalose-6-phosphate phosphatase (TPP) refer to catalytic activities" (emphasis in original).

Clearly WO 96/00789 and WO 93/17093 cannot suggest using trehalose-6-phosphate phosphatase and trehalose-6-phosphate synthase as inactive subunits to form an active enzyme. Because WO 96/00789 only discusses trehalose-6-phosphate phosphatase and trehalose-6-phosphate synthase, the contribution of this reference as a primary reference in the obviousness rejection is not clear from the record.

WO 93/17093 also describes the inter-relationship between the structural genes TSS1, TSL1 and TSL2, and the enzyme trehalose synthase which includes the active enzymes trehalose-6-phosphate-phosphatase and trehalose-6-phosphate synthase, as described above.

The Examiner does not address whether any one of TSS1, TSL1 or TSL2, when expressed alone in a plant, is active. WO 93/17093 on page 19, lines 25-33, however, discloses that the product

of the TLS2 gene has an activity similar to a trehalose-6-phosphatase, and the TSS1 gene product has an activity similar to a trehalose-6-phosphate synthase. Since TSS1 and TSL2 code for enzymes having an activity which is required to be absent, they cannot be used as inactive subunits in applicants' invention.

Without speculating whether TSL1 has any TPP or TPS activity, but merely for the sake of argument, applicants point out that even if TSL1 is assumed to be inactive, it is the only potentially inactive subunit disclosed. Applicants invention, on the other hand, requires two inactive subunits. Even if, *arguendo*, TSL1 is an inactive subunit, no other appropriate inactive subunit is disclosed by WO 93/17093 or by WO 96/00789.

Accordingly, it is not possible to express TSS1, TSL1 or TSL2 in any permutation that would result in at least one of the parent plants not having an active enzyme. Such a result is inconsistent with applicants' claims.

As applicants remarked in their August 23, 2002 Amendment, Hiatt et al. do not remedy the deficiencies of WO 93/17093 and WO 96/00789.

Accordingly, the combination of WO 93/17093, WO 96/00789, and Hiatt et al., even if proper, fails to teach or suggest every element of applicants' pending claims, and, clearly cannot provide the motivation and expectation of success, as required for a proper obviousness rejection. Therefore, the obviousness rejection based on WO 93/17093, WO 96/00789, and Hiatt et al. is improper and should be withdrawn.

Conclusion

In view of the preceding amendments and remarks, applicants maintain that the pending claims define patentable subject matter, request the Examiner to reconsider the claims, and earnestly solicit allowance of the pending claims.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Response. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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I hereby certify that this correspondence is being transmitted to the U.S. Patent and Trademark Office on the date indicated below by facsimile and is addressed to:
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